

The Rulemaking Process

Statutes are laws enacted by a legislature. Regulations are rules enacted by government agencies that have the same force of law as statutes. An agency receives its power to adopt regulations from statutes, and cites this authority at the end of each regulation. Regulations are rules adopted by a regulatory agency (like DPR) to carry out, interpret, or make specific the statutes enforced or administered by it, or to govern its procedures. The process of writing and adopting regulations is called rulemaking.

The State Administrative Procedures Act (APA) prescribes the process for putting regulations into place (Government Code 11340-11359). Among other requirements, the APA requires state agencies to give public notice when proposing regulations, to provide extensive documentation to support the need and authority for the regulation, to receive and consider public comments, to submit regulations and rulemaking files to the Office of Administrative Law (OAL) for review to ensure compliance with the requirements of the APA, and to have the regulations published in the California Code of Regulations (CCR). The role of OAL is to ensure that state agency regulations are authorized by statute, consistent with other law, and written in a comprehensible manner.

A regulation typically takes six months to a year to complete. The APA also allows agencies to file emergency regulations, provided the rulemaking meets certain criteria. However, unlike permanent regulations, which stay on the books until revised or repealed, emergency regulations expire within 120 days, and therefore must be followed by proposal of permanent regulations.

The CCR contains the text of the regulations that have been formally adopted by State agencies, reviewed and approved by OAL, and filed with the Secretary of State. The CCR consists of 27 titles (including the Food and Agricultural Code, where most pesticide-related regulations reside). The CCR is available at offices of County Clerks, county law libraries, and many public libraries. The Food and Agricultural Code is available online on DPR's Web site <www.cdpr.ca.gov>. The CCR is available at <<http://ccr.oal.ca.gov>>.

External Scientific Peer Review: The purpose of peer review is to uncover any technical problems or unresolved issues in a draft document so that the final publication will reflect sound technical information and analyses. It is a process for enhancing the scientific or technical work product.

As a result of a legislative mandate (Chapter 295, Statutes of 1997, SB 1320), no Cal/EPA board, department, or office "shall take any action to adopt the final version of a rule [that establishes a regulatory level, standard, or other requirement for the protection of public health or the environment . . . without submitting] . . . the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer entity for its evaluation."

The legislation mandated peer review by the National Academy of Sciences, the University of California, California State University, any similar institution of learning, or by a group of individual scientists recommended by the UC President.

FAC Section 14023(b) mandates that toxic air contaminant (TAC) health evaluation documents be reviewed by the Scientific Review Panel. (*See Chapter 4 for description of DPR's TAC program*). If regulations involve scientific documents already reviewed under the TAC program, the review by the TAC panel constitutes the legally required external peer review.

This external peer review process is in addition to the internal peer review that DPR typically conducts on its scientific documents. Also, the Food and Agricultural Code (Section 11454.1) directs OEHHHA to provide scientific peer review of DPR risk assessments (including risk characterization documents and exposure assessment documents). In addition, DPR has chosen to submit risk assessments to U.S. EPA for peer review. (*See next page for flowchart of rulemaking process.*)

FLOWCHART OF RULEMAKING PROCESS

PREPARATION OF THE PROPOSED ACTION FOR PUBLIC COMMENT

The Legislature gives limited lawmaking power to a state agency or department when, by passing a statute, it gives the agency a task. An agency or department must have delegated authority from the Legislature to adopt, amend, or repeal a regulation, and must demonstrate the necessity for the proposed regulatory action by presenting substantial evidence in the rulemaking record.

DPR: Conducts preliminary rulemaking activities, such as research and stakeholder workshops, and prepares proposed action including notice, regulation text, reason for regulation, and costs to state and local government and the economic impact on business.

Consultation with other agencies: Depending on the issues addressed in proposed regulations, DPR may consult with the Office of Environmental Health Hazard Assessment, the Air Resources Board, the Department of Food and Agriculture, or other agencies.

External scientific peer review: *If the regulations are based on new scientific studies or methodology, that science (not the regulations themselves) must be peer-reviewed by the University of California, National Academy of Sciences or similar approved institutions. Peer review must be completed before adoption of final regulations.*

DPR: Submits proposed action to the State Office of Administrative Law (OAL).

OAL: Reviews notice for compliance with legal criteria and filing requirements. If approved, notice published in OAL's *California Regulatory Notice Register* and on DPR Web site [www.cdpr.ca.gov], and mailed to interested parties.

PUBLIC COMMENT PERIOD (45-day minimum)

Public Comment: Begins when proposed action published. All rulemaking documents must be available for public review and comment. Hearings may be scheduled by DPR or by request. Written comments may be submitted via mail and e-mail. DPR must consider public input relevant to the proposal.

FINAL REVIEW AND ADOPTION

After resolution of public comments and other issues, the regulation is adopted.

DPR: Reviews comments, plus any new information from other sources, and decides whether they warrant changes to proposed action.

No changes or non-substantive changes

DPR: Changes that are "sufficiently" related require a 15-day notice for public comment on the revised text.

Changes to proposed action are necessary

DPR: Major changes "not sufficiently" related require a new 45-day notice.

DPR: Completes rulemaking record, with extensive documentation, including regulation text, final statement of reasons, and responses to all comments relevant to proposed action. DPR must explain how proposed action was changed to accommodate comments, or reasons for no changes. Rulemaking record must be submitted to OAL within one year of publication of notice.

OAL: Typically has 30 working days to determine whether to approve proposed action based upon legal criteria and on adequacy of response to comments.

OAL disapproves

DPR: May be possible to revise and resubmit to OAL. DPR can also abandon proposed action, and the rulemaking record automatically closes one year after publication in the Register.

OAL approves

Filing: New regulation is filed with the Secretary of State and printed in California Code of Regulations. Regulation typically goes into effect 30 days after filing.